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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,067

Applicant(s)

YOUNG ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ 08/23/04 04/23/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6, 10-15 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the first rod connecting portion" in line 25. There is insufficient antecedent basis for this limitation in the claim.

In claim 10, line 8, applicant states "...the shaft is slidable received..."

Appropriate correction is required.

In claim 22, line 22, applicant states "...the shaft is slidable received..."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, 16-23, 29-34, and 43-53, and 58 (including method claims), as best understood by the examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by Korhonen et al. (US Pat. 5,669,910).

Korhonen et al. disclose a cross-connector assembly (Fig. 2, ref. 16) for interconnecting a pair of orthopedic rods, the assembly comprising: an interconnection element (Fig. 4, ref. 30) including a first body having a first aperture (Fig. 4, hole near ref. 46) formed therein and a stud (Fig. 4, ref. 24a) extending from the body; a first rod connector (Fig. 4, ref. 18) including a first shaft (Fig. 4 below) the middle section of ref. 18, near the holes) terminating in a first rod engaging portion (Fig. 4 below) and a projection (Fig. 4, ref. 24) extending laterally from the first shaft and displaced axially along the first shaft from the spinal rod engaging portion, the first shaft and the projection slideably received within the first aperture (Fig. 2); a second rod connector (Fig. 4, ref. 28) including a second shaft (Fig. 4, the middle section of 28, between holes 35 and 38)) having a second body (Fig. 4 below) carried thereon, the second body having a second aperture (Fig. 4, ref. 38) formed therein, the second aperture having the stud received therein (Fig. 2) and a fastener configured to engage with the stud (Fig. 2, ref. 41). The first aperture defines a first axis extending through the first body and the stud can be positioned to lie substantially orthogonal to the axis.

The first aperture is non-circular, since it includes a rectangular portion (Fig. 4). The first shaft exhibits a substantially round cross-sectional profile (Fig. 4, ref. 18). The first rod connecting portion (Fig. 4, ref. 18) comprises a curved member configured to at

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least partially encircle a spinal rod (Fig. 1). The member can be considered curved since the edges around bore 23 are in the form of a circle. The first rod connecting portion comprises a threaded aperture (Fig. 4, ref. 23) extending into the curved member. The first shaft is substantially straight (Fig. 4, ref. 18). The first shaft is curved (Fig. 4, ref. 18). The shaft is nearly (substantially) straight, but there are curves on the shaft, such as the rounded edges along the outer perimeter and near the bore (Fig. 4). The second shaft is curved, since it has rounded edges and curved areas near the bore holes (Fig. 4). The first shaft can be slideably received within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances (column 1, lines 25-27). The second shaft is rotatable about an axis defined by the stud to vary at an angle defined by the first shaft and the second shaft. The first shaft and the second shaft are curved, since they both have rounded edges and curved areas surrounding the bores (Fig.4). The second aperture of the second shaft is configured to allow the second shaft to pivot along the axis defined by the stud. The first rod connector is rotatable about an axis defined by the first shaft. The second body on the second shaft includes a lower surface (Fig. 4, ref. 48) wherein engagement of the fastener to the stud can urge the lower surface to contact the first shaft and can clamp the first shaft in a first orientation relative to the second shaft. The first rod connector can be rotated about an axis defined by the first shaft. Rotation of the first rod connector can induce the projection to contact the first body and inhibit the removal of the first shaft from the first aperture. The first rod connector is rotatable about an axis defined by the stud. The second rod connector is rotatable about an axis defined by the

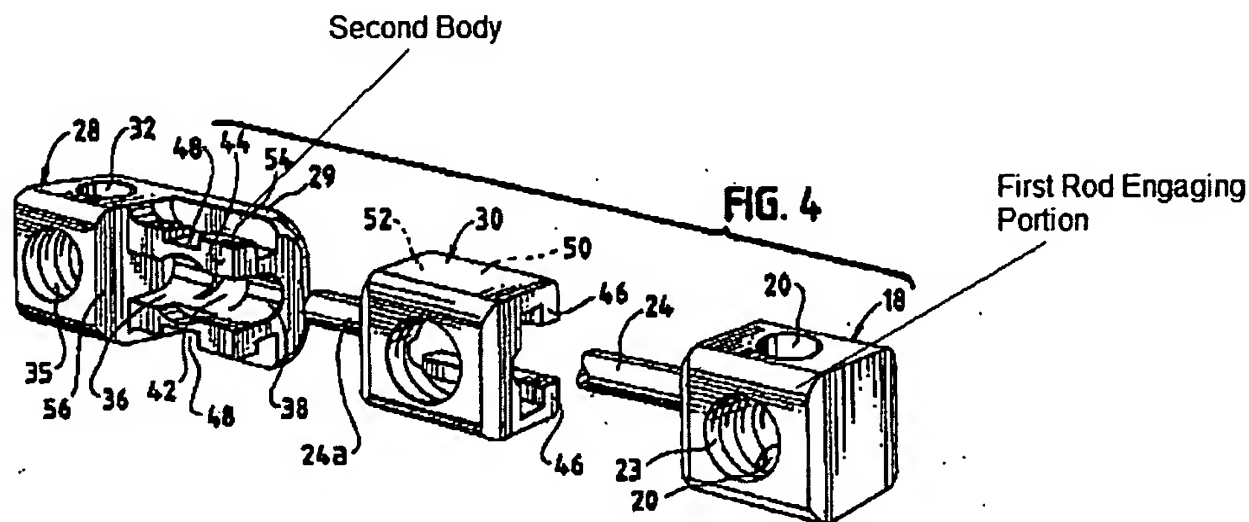
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stud. The first shaft of the first rod connector and the second shaft of the second rod connector are curved, since they both have rounded edges and curved areas surrounding the bores (Fig.4). The first shaft is slideably received within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances (column 1, lines 25-27). The assembly further comprises a first spinal rod (Fig. 1, ref. 12) secured to the first rod engaging portion and a second spinal rod (Fig. 1, ref. 14) secured to the second rod engaging portion, wherein the first spinal rod can be positioned to lie non-parallel to the second spinal rod.

Engagement of the fastener to the stud can secure the second rod connector in a selected orientation. The assembly further comprises a first spinal rod secured to the first rod engaging portion (Fig. 1, ref. 12) and a second spinal rod secured to the second rod engaging portion (Fig. 1, ref. 14), wherein the first spinal rod can be positioned to lie non-parallel to the second spinal rod. The first spinal rod defines a first plane and the second spinal rod is positioned to lie in a plane different from the first plane. A flat, two dimensional plane can radially run through the first rod at any angle, which would allow some planes to exist that run through the first spinal rod, but lie outside the space that the second spinal rod is in. The first rod engaging portion (Fig. 4, ref. 18) comprises a hook sized to at least partially encircle a spinal rod, the hook extending laterally from the first shaft in a first direction and wherein the projection extends laterally from the first shaft along the first direction. The definition of hook, according to the Merriam-Webster Online Dictionary, is "a curved or bent device for catching, holding, or pulling." The rod engaging portion can be considered a hook, because it has curves (around the circular

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bores), and it is used for holding the rod. It is extending laterally from the shaft, since it is coming from the side of the shaft (Fig. 4). The projection defines a finger, lobe, or ridge. The projection can be considered a finger (Fig. 4, ref. 24a). At least one of the first shaft or the second shaft has a smooth exterior surface (Fig. 4) and a round or oval cross-sectional profile. Considering part of the projection (Fig. 4, ref. 24a) as part of the shaft, the shaft has a round cross-sectional profile. The first and second shafts are configured to nest with each other (Fig. 2).



Korhonen et al. further disclose a method of treating a spinal defect, the method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 1 (column 3, lines 16-22).

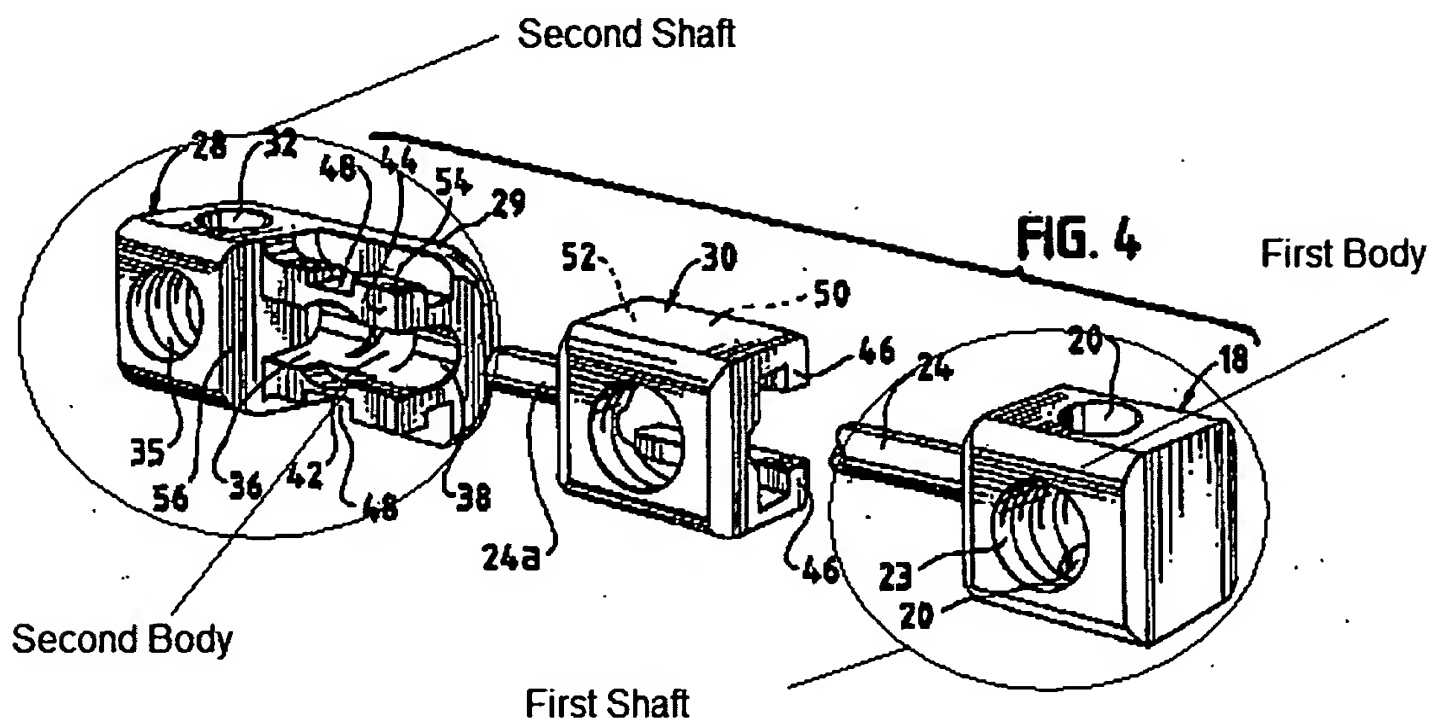
Korhonen et al. further disclose a cross-connector assembly for interconnecting a pair of orthopedic rods, the assembly comprising: a first rod connector (Fig. 4, ref. 18)

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including a first shaft (Fig. 4 below) terminating in a first body (Fig. 4 below) having a channel (Fig. 4, ref. 20) therethrough; a second rod connector (Fig. 4, ref. 28) including a second shaft (Fig. 4 below) defining a longitudinal axis and terminating on a first end with a rod engaging portion (Fig. 4, ref. 35) and on an opposite second end with a second body (Fig. 4 below), the second body having a first aperture (Fig. 4, ref. 38) therein defining a first central axis positioned to lie in a plane with the longitudinal axis, the second rod connector also including a second aperture (Fig. 4, ref. 36) therein defining a second central axis positioned to lie at an angle to the first central axis; an insert which can engage the first shaft of the first rod connecting member extending through the first aperture and can be positioned in the second body and in communication with the second aperture; and a fastener (Fig. 2, ref. 41) extending through the second aperture of the second body (Fig. 2) and can engaging one or more of the insert, the second body of the second rod connector, or the first shaft of the first rod to secure the orientation of the first rod connector relative to the second rod connector. The first shaft of the first connector is straight (Fig. 4). The first shaft of the first connector is curved, since the edges are rounded or curved (Fig. 4). The first aperture and the second aperture intersect (Fig. 4). The fastener can engage with both the insert and the first shaft. The fastener can engage the insert thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member. The fastener can engage the first shaft thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member. The fastener can engage the second body of the second rod connector

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thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member.

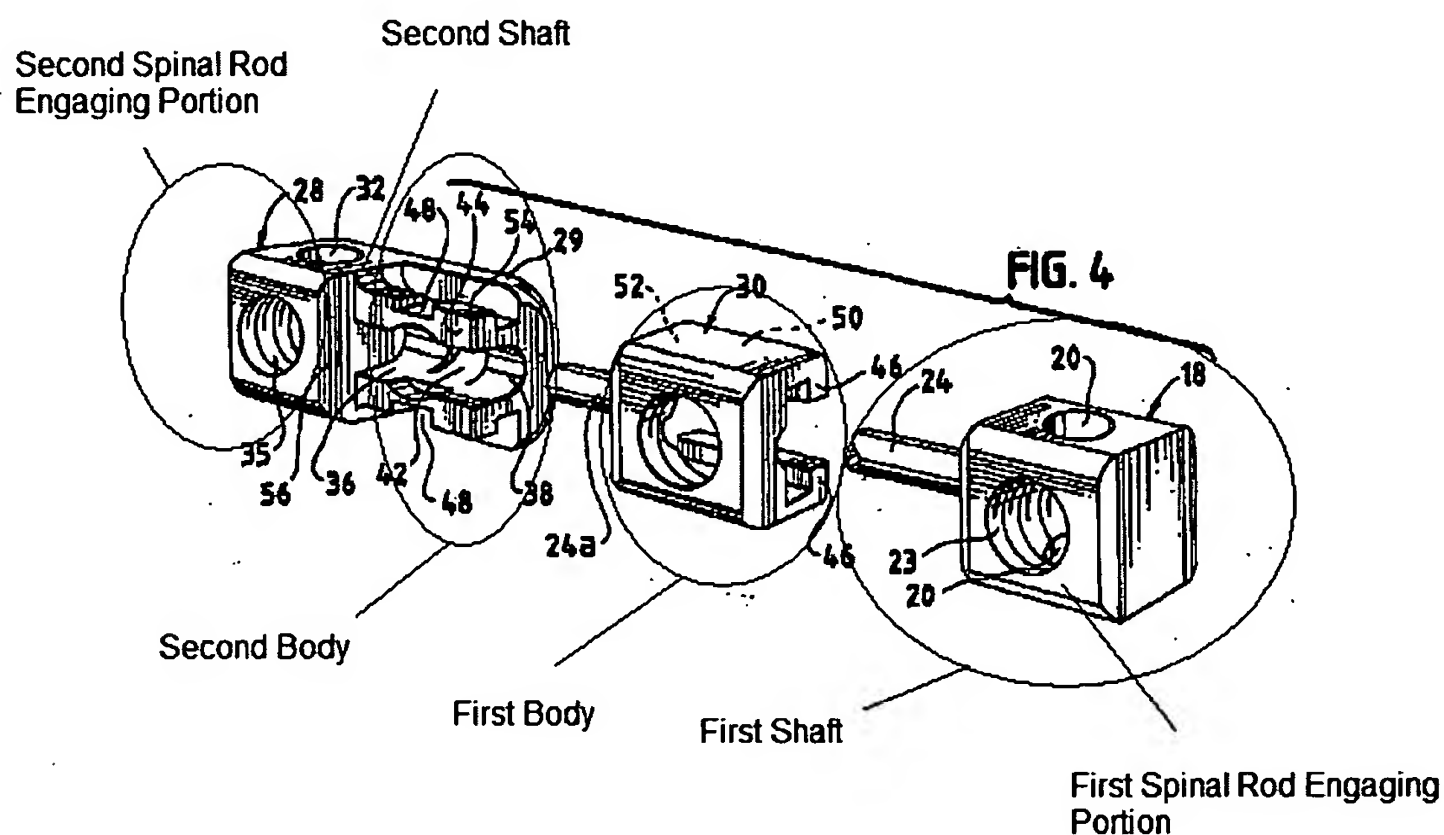


Korhonen et al. further disclose a method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 44 (column 3, lines 16-22).

Korhonen et al. further disclose a cross connector comprising an interconnection element (Fig. 4, ref. 30) including a first body having an aperture (Fig. 4, near ref. 46) formed therein and a stud (Fig. 4, ref. 24a) extending from the body; a first spinal rod connector (Fig. 4, ref. 18) including a first shaft having a proximal end received within the aperture (Fig. 2) and a distal end carrying a first spinal rod engaging portion configured to at least partially encircle a spinal rod; a second spinal rod connector (Fig. 4, ref. 28) having a second body on a proximal end, a second spinal rod engaging

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portion on a distal end and a second shaft extending therebetween, wherein the body includes a second aperture (Fig. 4, ref. 38) having the stud received therein; and a single fastener (Fig. 2, ref. 41) to secure the first and second spinal rod connectors to each other at a user defined orientation relative to each other. The first shaft comprises a protuberance extending laterally therefrom, the protuberance sized to be received within the first aperture. The first shaft comprises a protuberance (Fig. 4, ref. 24) extending laterally therefrom and the protuberance is sized to be received within the first aperture.



Korhonen further disclose a method of treating a spinal defect, the method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 53 (column 3, lines 16-22).

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With regard to the statements of intended use and other functional statements (e.g. ...configured to engage with said stud..., to allow the first rod engaging portion..., ...engagement of the fastener to the stud urges the lower surface to contact the first shaft...), they do not impose any structural limitations on the claims distinguishable over the cross connector assembly of Korhonen et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 16-23, 29-36 and 39-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korhonen et al. (US Pat. 5,669,910) in view of Schluzas (US Pat. 6,554,832 B2).

Korhonen et al. disclose the claimed invention, except for an insert, and the insert and the first aperture defining a ball and socket joint.

Schluzas discloses a cross-connector assembly with an insert (Fig. 2, ref 48) and a first aperture (Fig. 2, near ref. 50), and the insert and the first aperture forming a ball and socket joint (Fig. 4), in order to allow the connecting rod to pivot (column 2, lines 36-39) and conform to the specific area of the spine that is being stabilized (Fig. 1). The insert is configured to at least partially encircle the first shaft (Fig. 2, ref. 52 and 42). The insert is configured to at least partially encircle the stud, since the stud and the first shaft have approximately same diameter (Korhonen et al., Fig. 2). The insert can be placed in the second aperture to define a ball and socket joint, similar to the ball and socket joint of the first aperture. The insert is substantially spherical on one end (Fig. 2, ref 50) and substantially cylindrical on the other end (Fig. 2, the end near ref. 40). The insert in combination with the first body can restrict movement of the first shaft to inhibit disassembly of the apparatus. The insert can be positioned within the second body and is configured to at least partially encircle the second shaft.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the cross-connector assembly of Korhonen et al. with the insert (Fig. 2, ref. 48) and first aperture (Fig. 2, near ref. 50) of Schluzas, and the insert and the first aperture forming a ball and socket joint (Fig. 4) of Schluzas, in order to allow the connecting rod to pivot (column 2, lines 36-39) and conform to the specific area of the spine that is being stabilized (Fig. 1).

Claims 1-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korhonen et al. (US Pat. 5,669,910) in view of Schluzas (US Pat. 6,554,832 B2), and further in view of Sherman et al. (US Pat. 5,976,135).

Korhonen et al. in view of Schluzas disclose the claimed invention except for the washer and the washer having splines and the second spinal rod connector having a lower surface, which has a second set of splines.

Sherman et al. disclose a lateral connector assembly comprising a washer (Fig. 7, ref. 55) and the washer having splines (Fig. 7, ref. 60) and recesses (Fig. 6, ref. 58) and the second spinal rod connector having a lower surface (Fig. 11, ref. 72), which has a second set of splines (Fig. 11, ref. 82) which can matingly engage the splines of the washer, which allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19). The washer is made from a deformable material, since any material will deform when pressure is applied to it. The washer is capable of deforming when the fastener engages the stud. Engagement of the fastener can frictionally engage the washer to the first shaft of the first rod connector. The washer is capable of being carried by the stud and positioned between the stud and the second aperture of the second rod connecting member.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the cross-connector assembly of Korhonen et al. in view of Schluzas with the a washer and the washer having splines and the second spinal rod connector with a lower surface, which has a second set of splines of Sherman et al., in order to allow the lateral connector to assume variable angular

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positions with respect to the washer (column 7, lines 1-19), which would be beneficial with the ball and socket joint of Schluzas (Schluzas, Fig. 4).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER